510(k) SUMMARY
PelvX Gellhorn

DesChutes Medical Products, Inc.
1011 SW Emkay Drive, Suite 104
Bend, OR 97702
Date Prepared: 7/21/00

1. CONTACT PERSON

Denise Bestwick
Phone : (541) 385-0350
Fax : (541) 382-2079

2. NAME OF THE MEDICAL DEVICE

Classification name : Vaginal Pessary
Common/usual name : Vaginal Pessary
Proprietary name : PelvX Gellhorn

3. DEVICE CLASSIFICATION

PelvX Gellhorn Vaginal Pessary is classified by the FDA under the heading of Vaginal Pessary (21 CFR Section 884.3575) as a Class II device with Product Code: 85HHW.

4. STATEMENT OF SUBSTANTIAL EQUIVALENCE

PelvX Gellhorn Vaginal Pessary is substantially equivalent to the Milex Gellhorn pessary, manufactured by Milex Products, Inc., Chicago, IL 60631.

A comparison of the PelvX Devices versus the Milex Devices is presented in Tables 1 and 2.

5. INTENDED USE

The PelvX Gellhorn Vaginal Pessary intended for the support of third degree uterine prolapse and procidentia.

6. DESCRIPTION OF DEVICE

The PelvX Gellhorn Vaginal Pessary is a pessary intended for the support of third degree uterine prolapse and procidentia. This pessary is designed to help support internal pelvic organs when the prolapse (collapse) is moderate to severe. The PelvX® Gellhorn is made of a medical grade silicone. It is the shape of a concave disc with a stem protruding from the disc. The disc supports the uterus. The cervix rests behind the flat base of the pessary and the stem of the pessary protrudes into the vagina to prevent the device from turning.

7. SUBSTANTIAL EQUIVALENCE COMPARISON

Tables 1 and 2 demonstrate the relative regulatory classifications and features of the DesChutes Gellhorn compared to the Milex Gellhorn.

The common and classification names for these products are identical. In addition, both of these devices are prescription devices. These vaginal pessaries are reusable devices which must be fitted, checked for continuing fit, and monitored for developing problems by medical personnel. The DesChutes and Milex Gellhorns have identical intended uses. The contraindications for their use are also the same. The pessaries are supplied clean but not sterile. Cleaning procedures are also the same. Both devices come in a variety of sizes for fitting.

There are several differences between the DesChutes and Milex products. First, DesChutes explicitly states that these are single patient devices while Milex is silent on this point. Second, DesChutes adds a precaution that the pessary should be removed before sexual intercourse. The colors of the two devices are different. The Milex Gellhorn is a faint yellow opaque and the DesChutes product is purple. The material and color additive used in PelvX were fully tested for Biocompatibility. Refer to Section 8 of this summary for a description of the biocompatibility assessment. Finally, the pessaries are packaged differently which does not affect the intended use, safety or performance of the product.

Table 1—Comparison of Regulatory Classifications

Category	DesChutes Medical Products PelvX Gellhorn	Milex Gellhorn Flexible Folding Pessary
Common or usual name	vaginal pessary	vaginal pessary
Classification name Product Code	884.3575 Vaginal pessary 85HHW	884.3575 Vaginal pessary 85HHW
Prescription device	yes	yes

Table 2 —Comparison of Device Features

Feature	DesChutes Medical Products PelvX Gellhorn	Milex Products Gellhorn
Intended Use	support of third degree uterine prolapse and procidentia	effective support of third degree prolapse or procidentia
Single patient device	yes	implied but not specifically stated
Single use or reusable	reusable	reusable
Must be initially fitted by medical personnel	yes	yes
Requires regular visits to medical personnel for checking	yes	yes
Contraindications	1) pelvic infections or lacerations 2) non-compliant patients 3) endometriosis 4) sexually active patient	1) pelvic infections or lacerations 2) non-compliant patients 3) endometriosis 4) sexually active patient
Cautions	1) individual use only 2) if pregnant, seek the advice of your practitioner before using 3) remove pessary before sexual intercourse	(not clear in labeling)
Sterilization status	clean, but not sterile	clean, but not sterile
Foldable	yes	yes
Maintenance	clean with warm water and soap when removed	clean with water and mild soap when removed
Material	medical grade silicone	medical grade silicone
Color additives	yes	yes
Number of models	6 (3 - 8)	9 (1-9)
Sizes	2", 2.25", 2.5", 2.75", 3", 3.25	1.5", 1.75", 2", 2.25", 2.5", 2.75", 3", 3.25", 3.5"
Instructions	"Practitioner Guide" and "Patient Guide"	"Doctor/Nurse Fitting Instruction" and "Instructions for Pessary Wearers"
Packaging	plastic bag inside paperboard box with label	plastic clamshell with instructions for use visible

8. SUMMARY OF SAFETY TESTING

The DesChutes PelvX Gellhorn is made of a known medical grade silicone. Extensive testing of this silicone was as follows:

1. CYTOTOXICITY STUDY USING THE ISO ELUTION METHOD
2. ISO SENSITIZATION STUDY IN THE GUINEA PIG (MAXIMIZATION METHOD)
3. SENSITIZATION IN THE GUINEA PIG (MAXIMIZATION METHOD)
4. VAGINAL IRRITATION STUDY IN THE RABBIT WITH HISTOPATHOLOGY –14 DAYS
5. ACUTE SYSTEMIC TOXICITY STUDY IN THE MOUSE (EXTRACT)
6. RABBIT PYROGEN STUDY (MATERIAL MEDIATED)
7. ISO MUSCLE IMPLANTATION STUDY IN THE RABBIT WITH HISTOPATHOLOGY (ONE WEEK)
8. ISO MUSCLE IMPLANTATION STUDY IN THE RABBIT WITH HISTOPATHOLOGY (FOUR WEEKS)
9. ISO MUSCLE IMPLANTATION STUDY IN THE RABBIT WITH HISTOPATHOLOGY (TWELVE WEEKS)

The silicone material used is the same as for the DesChutes Donut Pessary (510(k) #974117). This testing regime was was determined to satisfy the requirements in "General Purpose Memorandum G95-1 Use of International Standard ISO-10993" for devices in contact with mucosal membranes for between 24 hours and 30 days. The test results support the position that this material is substantially equivalent to the other materials used for similar purposes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 8 2000

Ms. Denise Bestwick
Vice President, Regulatory & Quality System
DesChutes Medical Products, Inc.
1011 SW Emkay Drive, Suite 104
Bend, Oregon 97702

Re: K002329
PelvX Gellhorn Vaginal Pessary 603-608
Dated: July 28, 2000
Received: August 1, 2000
Regulatory Class: II
21 CFR 884.3575/Procode: 85 HHW

Dear Ms. Bestwick:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Statement of Indications for Use

510(K) Number (if known): K002329

Device name: PelvX Gellhorn Vaginal Pessary

Indications for Use:

The PelvX Gellhorn Vaginal Pessary is a vaginal pessary intended for the support of third degree uterine prolapse and procidentia.

(Please do not write below this line)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002329